REMARKS

Status of the Claims

Claims 1-41, 43-45, 47-61, and 74-87 are pending in the present application, Claims 42, 46, and 62-73 having been canceled in the present amendment as being directed to a non-elected invention. The Examiner notes that Claims 4-6, 10-14, 17-19, and 36 have been withdrawn from consideration, as being directed to a separate species of the elected invention, but will be entitled to consideration upon allowance of a generic claim. Claims 4, 21, 50, 57, 61, and 82 have been amended to correct minor errors.

Restriction Requirement and Affirmation of Telephone Election

The Examiner issued a telephone restriction on March 3, 2006. At that time, applicant's attorney elected Group 1, Claims 1-41, 43-45, 47-61, and 74-87. Applicant's attorney further elected Species 2, encompassing Claims 7, 16, 48, 56, and 60. Applicant hereby affirms that election.

Amendment to the Specification

The Examiner has noted that the present application is a continuation-in-part of a recently issued application and required that the patent number of the recently issued application be incorporated into the RELATED APPLICATIONS section. Applicant has amended this section to include the corrections requested by the Examiner. Accordingly, the objection to the specification should be withdrawn.

Rejections of Claims under 35 U.S.C.§ 112, Second Paragraph

The Examiner has rejected Claims 1-3, 7-9, 15, 16, 20-35, 37-41, 43-45, 47-61, 75, 78, 82-84, and 87 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as his invention. In particular, the Examiner asserts that claimed structural elements cannot perform the function of training and testing/evaluating personnel. The Examiner further asserts of the following terms are unclear: "to determine the physiological response for the medical training simulate to emulate" (Claim 78), "a meter," "a pump," "a neural network," and a "human nervous system." The Examiner also points out that the term "the processor" in Claim 82 lacks antecedent basis.

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The Standard for Indefiniteness

The Examiner has issued numerous indefiniteness rejections. While some of the rejections appear well reasoned, others do not appear reasonable when analyzed with respect to the ability of one of ordinary skill in the art to ascertain the scope of these claims.

MPEP 2173.02 discusses how a question of indefiniteness is to be analyzed. In particular, this section of the MPEP indicates that "[S]ome latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the Examiner might desire." Furthermore, MPEP 2173.02 makes it clear that definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Thus, the claim language need not be the best possible claim language, but must merely enable one of ordinary skill in the art to ascertain what is being claimed. With respect to at least some of the most recent indefiniteness rejections, it appears that one of ordinary skill in the art should not have any trouble interpreting the claims and understanding their scope. Should the Examiner feel it necessary to maintain any current indefiniteness rejections, or raise further indefiniteness rejections, applicant respectfully requests the Examiner to articulate why one of ordinary skill in the art, given the content of the present application and the teachings of the prior art, would be unable to interpret the language at issue in the claims.

The Examiner's Assertion That the Claimed Elements Cannot Perform the Claimed Function

The Examiner has asserted that the claimed structural elements cannot perform the function of training and testing/evaluating of personnel to properly perform the simulated medical procedure, as claimed. Unfortunately, the Examiner provided no articulation supporting such an assertion. The Examiner did not provide any reasons for concluding why one of ordinary skill in the art, given the content of the present application and the teachings of the prior art, would be unable to ascertain the scope of the claims. Without having the benefit of ***any*** articulation providing a logical basis for the rejection, applicant is hard-pressed to understand such a rejection, much less respond.

This particular rejection encompasses independent Claims 1, 2, 45, 57, 74, and 79.

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Claim 1 defines a physiological training and evaluation simulator suitable for training and testing personnel, comprising a simulated physiological structure and a circuit including a conductive elastomer. The specification as filed describes in great detail a plurality of different medical training simulators, each including a simulated physiological structure (such as tissue, a joint, an organ, or a bone), and an evaluation circuit that incorporates a conductive elastomer. The disclosure clearly describes how the conductive elastomer-based circuit is an evaluation circuit configured to enable feedback relating to a simulated procedure to be provided. Multiple embodiments of such an evaluation circuit are explicitly described in the specification. Applicant believes he is the first to provide an apparatus suitable for training purposes that incorporates a simulated physiological structure and an evaluation circuit incorporating a conductive elastomer, hence the relatively broad language of Claim 1. It is well accepted according to US PTO policy and procedure that breadth is not indefiniteness. MPEP 2173.04 explicitly states that *"If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. § 112, second paragraph."* Applicant has clearly described many different training devices including simulated physiological structures and circuits configured to evaluate performance which include a conductive elastomer. There is simply no evidence that one of ordinary skill in the art would not be able to understand the scope of the protection being sought, particularly given the many different embodiments disclosed by applicant. With respect to simulated physiological structures, applicant has described in great detail how many different simulated physiological structures (joints, bones, tissue, organs) can be incorporated into training simulators to measure the performance of an individual utilizing such a simulator to perform a simulated medical procedure. With respect to circuits incorporating a conductive elastomer, applicant has described in great detail how many different configurations use a conductive elastomer for evaluation circuits, each of which includes the basic elements of a simulated physiological structure and a circuit incorporating a conductive elastomer. Since there is no evidence that one of ordinary skill in the art would not be able to understand the language employed in Claim 1 as well as the scope of protection being sought, this rejection should be withdrawn. Should the Examiner disagree, applicant respectfully requests that the Examiner provide a detailed articulation of the logic employed to conclude that the scope of Claim 1 could not be ascertained by one of ordinary skill in the art.

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Claim 2 defines a physiological training and evaluation simulator suitable for training and testing personnel, comprising a simulated physiological structure and an evaluation circuit including a conductive elastomer, the evaluation circuit configured to provide a signal relating to a simulated procedure being performed on the simulated physiological structure, the conductive elastomer enhancing the realism of the simulator. Once again, the specification as filed provides a great level of detail as to many different embodiments of training devices incorporating both simulated physiological structures and circuits incorporating a conductive elastomer. The specification also provides details with respect to how elastomeric materials can enhance the realism of a training device. Claim 2 is entirely consistent with the specification as filed, and there is absolutely no evidence that one of ordinary skill in the art would not be able to understand the scope of Claim 2, after reviewing the specification as filed. As described in detail in the specification, training devices incorporating simulated physiological structures and circuits including conductive elastomers can be used for training and testing of personnel with respect to performing simulated medical procedures in a great many ways. Should the Examiner disagree, applicant respectfully requests that the Examiner provide a detailed articulation of the logic employed to conclude that the scope of Claim 2 could not be ascertained by one of ordinary skill in the art.

Claim 45 again broadly recites a training device (a medical training simulator suitable for medical skills training and evaluation) comprising a simulated physiological structure and an evaluation circuit incorporating a conductive elastomer. Claim 45 is not indefinite for substantially the same reasons discussed above. Should the Examiner disagree, applicant respectfully requests that the Examiner provide a detailed articulation of the logic behind concluding that the scope of Claim 45 could not be ascertained by one of ordinary skill in the art.

Claim 57 recites a method for making a training device (a medical training simulator suitable for medical skills training and evaluation), which includes the steps of identifying a specific physiological structure that should be simulated, determining a simulated medical procedure that the training device will be used to simulate, and constructing the device such that it includes the simulated physiological structure identified, and an evaluation circuit including a conductive elastomer, where the evaluation circuit is configured to provide feedback relating to the simulated medical procedure. Claim 57 is not indefinite for substantially the same reasons discussed above. Should the Examiner disagree, applicant respectfully requests that the Examiner provide a detailed

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articulation of the logic supporting a conclusion that the scope of Claim 57 could not be ascertained by one of ordinary skill in the art.

As discussed in detail above, the language employed in each independent claim is clearly supported by the specification as filed, and there is no evidence to conclude that one of ordinary skill in the art would be unable to ascertain the scope of the protection being sought (that is the standard for evaluating an indefiniteness rejection). Because dependent claims are patentable for at least the same reasons as the claims upon which they depend, each claimant depending from Claims 1, 2, 45, and 57 is also patentable. Accordingly, the rejection of Claims 1-3, 7-9, 15, 16, 20-35, 37-40, 42-57, and 60 as being indefinite should be withdrawn.

The Indefiniteness of the Term to Emulate in Claim 78

The Examiner has asserted that the following phrase is indefinite, because the meaning of the phrase is not understood: *"... wherein the indication produced by the conductive elastomer-based evaluation circuit is used to determine a physiological response for the medical training simulator to emulate."* The first paragraph of page 5 provides the following discussion as to specific physiological responses medical training simulators in accord with the present invention can be configured to emulate.

> The feedback can also be a simulated physiological response initiated in the simulated physiological structure, such as a change in a simulated heartbeat, the simulated physiological response being consistent with the simulated procedure.

Other specifically disclosed simulated responses include a simulated muscular response and a change in a simulated respiratory rate. Given the disclosure provided by the specification, there appears to be no reasonable basis for concluding that an artisan of ordinary skill would not recognize that the indication produced by the conductive elastomer-based evaluation circuit can be used to emulate (i.e., to simulate) a physiological response. Accordingly, the rejection of Claim 78 as being indefinite should be withdrawn. Should the Examiner disagree, applicant respectfully requests that the Examiner provide a detailed articulation of the logic supporting a conclusion that the scope of Claim 78 could not be ascertained by one of ordinary skill in the art.

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The Indefiniteness of the Term "Meter" in Claim 23

The Examiner has asserted that the term "meter" is indefinite, because the meaning of the term is not understood. The first paragraph of page 35 provides the following discussion relating to meters.

> Circuit 330 is incomplete, as indicated by a gap 336. When the circuit is completed (using any of the actions described below), a current flowing through the circuit actuates an indicator 334, which may be visual, such as a light or meter, and/or an audible indicator.

Clearly, a meter provides a visual indication to a user. Such meters are ubiquitous, and are extremely well-known in the art. Both analog and digital meters are widely used. Analog meters are particularly ubiquitous, and are incorporated into a tremendous variety of electronic devices where it is desirable to provide a visual indication of some phenomenon to a user, such as stereo equipment and volt meters. There appears to be no logical basis for concluding that an artisan of ordinary skill would not recognize that meters are widely used to provide a visual indication of some phenomenon to a user, particularly because the Examiner has had no trouble citing a relevant reference that does include such a meter (Pugh). Accordingly, the rejection of Claim 23 as being indefinite should be withdrawn. Should the Examiner disagree, applicant respectfully requests that the Examiner provide a detailed articulation of the logic supporting a conclusion that the scope of Claim 23 could not be ascertained by one of ordinary skill in the art.

The Indefiniteness of the Term "Servo/Pump" in Claims 33, 83 and 84

The Examiner has asserted that the terms "servo" and "pump" are indefinite, because the meanings of the terms are not understood. The second paragraph of page 14 provides the following discussion as to specific physiological responses that can be implemented using a servo or pump.

> Conductive elastomer-based evaluation circuits incorporated into simulated physiological structures can be used in a variety of different ways. Three significant uses include collection of data which is stored for later use, collection of data to be processed to provide some contemporaneous feedback (such as a visual or an audible indication that a procedure has been performed correctly or incorrectly, provided to a trainee, a proctor, or both), and collection of data which is analyzed and may be used to trigger a simulated physiological response in the simulated physiological structure (i.e. a change in a simulated heartbeat, a simulated muscular response, a change in a simulated respiratory rate, etc., implemented by controlling a servo or pump).

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Servos (or servo motors or other types of actuators) and pumps are extremely ubiquitous, and widely employed when actuation of a component or physical movement is required. The specification as filed clearly discloses that both pumps and servos can be used when mechanical movement is required (i.e., a change in a simulated heartbeat, a simulated muscular response, a change in a simulated respiratory rate). There appears to be no logical basis for concluding that an artisan of ordinary skill would not be familiar with servos, servo motors, and pumps, particularly when applicant specifically identifies the functions such servos and pumps implement. Accordingly, the rejection of Claims 33, 83, and 84 as being indefinite should be withdrawn. Should the Examiner disagree, applicant respectfully requests that the Examiner provide a detailed articulation of the logic supporting a conclusion otherwise.

The Indefiniteness of the Term "Neural Network" in Claims 37 and 87

The Examiner has asserted that the term "neural network" is indefinite, because the meaning of the term is not understood. The second paragraph of page 76 provides the following discussion as to actual neural networks present in the human body and a simulated neural network implemented in the present invention.

> In another embodiment, network 512 is distributed throughout human patient simulator 510 so that it corresponds to the configuration of the neural network present in human anatomy. The human neural network is designed to collect electrical impulses from substantially the entire body and to transmit those impulses to the brain. A simulated neural network would similarly be used to collect electrical signals from substantially all of human patient simulator 510, and these signals will be transmitted to and analyzed by a processor 516. It should be understood that communication with processor 516 can be bidirectional, such that commands to actuate servos coupled to network 512 can flow from processor 516, through network 512, and to the servo (or other controllable component).

As described in the specification is filed, one aspect of the present invention is to incorporate an evaluation circuit that is implemented as a network which corresponds to the neural network in the human body (i.e., the nerves within the human body). Thus, if a particular portion of a simulated physiological structure is manipulated, the simulated neural network will send signals generally analogous to the signals which would be sent within the human body when a portion of the human body is manipulated. There is simply no evidence that an artisan of ordinary skill would not be able to comprehend such language, or be unable to ascertain the scope of Claims 37 and 87. Accordingly,

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the rejection of Claims 37 and 87 as being indefinite should be withdrawn. Should the Examiner disagree, applicant respectfully requests that the Examiner provide a detailed articulation of the logic supporting a conclusion to the contrary.

The Indefiniteness of the Term "Human Nervous System" in Claims 87

The Examiner has asserted that the term "human nervous system" is indefinite, because the meaning of the term is not understood. As disclosed in the specification as filed, some medical simulators in accord with the present invention can include conductive elastomers configured to resemble nerves found in the human body (at least in regard to the ability of a human nerve to convey an electrical impulse). For example, the last paragraph on page 63 reads as follows:

> It should be understood that as opposed to a conductive fabric, a conductive yarn or thread could be used, particularly for coupling to switches or servos included within a medical model. Note that a conductive yarn (i.e. a textile coated with a conductive material) more realistically simulates nerves than would a conventional metallic wire encapsulated in an insulative sheath.

As discussed above with respect to the rejection of Claims 37 and 87, some embodiments explicitly disclosed in the specification as filed are medical trainers that include a simulated neural network (i.e., the trainers include simulated physiological structures that correspond to the neural network/nervous system of the human body). FIGURE 24 specifically illustrates an array of conductive elastomers configured to achieve a simulated neural network coupling a plurality of different simulated physiological structures to a processor, much as nerves couple major organs and other physiological structures to the brain. There is simply no credible evidence that an artisan of ordinary skill would not be able to comprehend such language, or be able to ascertain the scope of Claim 87. Accordingly, the rejection of Claim 87 as being indefinite should be withdrawn. Should the Examiner disagree, applicant respectfully requests that the Examiner provide a detailed articulation of the logic supporting a contrary conclusion.

The Antecedent Basis Rejection of Claim 82

The Examiner properly noted that there is no antecedent basis for the term "the processor" in Claim 82, the claim previously referring instead to a "controller." Appropriate correction has been made to correct this inadvertent error.

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Obviousness Rejections Based on a Combination of D'Antonio and Hon

The Examiner has rejected Claims 1-3, 7-9, 15, 16, 20-22, 31, 32, 34, 35, 45, 47-54, 56-61, 74-82, and 85 under 35 U.S.C. §103 as being obvious over Hon (U.S. Patent No. 4,907,973) in view of D'Antonio (U.S. Patent No. 5,510,605). Essentially, the Examiner argues that Hon discloses each element in the claims, except the conductive elastomer-based evaluation circuit. The Examiner notes that D'Antonio discloses an equivalent conductive elastomer-based evaluation circuit and concludes that it would have been obvious to one of ordinary skill in the art to modify Hon's simulator to incorporate the conductive elastomer-based evaluation circuit disclosed by D'Antonio. Applicant respectfully disagrees for the following reasons.

Significantly, D'Antonio discloses the use of various types of switching elements in electronic ***sports*** equipment (or sports equipment, such as a ski binding, incorporating electronic circuits). The Examiner has thus failed to provide a prior art reference that shows the use of a conductive elastomer-based circuit in a physiological simulator for medical training. In patent terms, the D'Antonio reference is not analogous art, and it appears that the Examiner has failed to establish a *prima facie* basis for rejection, since one of ordinary skill in the art of medical simulators would not be led to review prior art related to sports equipment. Neither reference provides any indication that one of ordinary skill in the art would recognize that conductive elastomers would provide any benefit when incorporated into a physiological simulator for medical training.

It is well-established that the suggestion/motivation element *is required* to establish a *prima facie* prime case of obviousness. Such policy and procedure is articulated in the following excerpts from case law and the MPEP:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference(s) or to combine reference teachings to produce the claimed invention. Second, there must be a reasonable expectation of success in making such a combination. Finally, the prior art reference (or references when combined) must teach or suggest all elements or steps recited in the claim. *In Re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

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MPEP § 2141 standards for determining obviousness

(A) The claimed invention must be considered as a whole;

(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined. (Emphasis added.)

Clearly, a proper obviousness rejection requires not only identifying art that discloses each element recited in a claim, but there must also be some identifiable motivation to combine such references, and the motivation must arise without the benefit of impermissible hindsight.

Simply because a plurality of references in combination disclose each element of an invention does not merit the conclusion that it would have been obvious to combine the references. Some motivation, other than hindsight, must be present in the references, that would lead one of ordinary skill to make such a combination. With respect to at least some of the rejections raised by the Examiner, applicant believes that impermissible hindsight has been used in place of any motivation or suggestion articulated in the prior art, or in the knowledge generally available to one of ordinary skill. With respect to any obviousness rejections maintained or further raised in any future Office Actions, applicant respectfully requests the Examiner to more fully articulate reasons why an artisan of ordinary skill would have been lead to modify the prior art to achieve an equivalent of what applicant has claimed, particularly where the references themselves do not provide the required suggestion/motivation.

Referring once again to the proposed combination of Hon and D'Antonio, not only is D'Antonio non-analogous art, neither reference teaches or suggests that conductive elastomers could be used to enhance the realism of a simulated physiological structure, or a medical simulator including a simulated physiological structure. Applicant's specification as filed goes into considerable detail describing the benefits that can be achieved with respect to enhancing the realism of medical training devices that conductive elastomers provide. Such a teaching is absent from the cited art. Significantly, Hon is not particularly concerned with the realistic look of the training model, because Hon emphasizes creating a virtual reality environment that is displayed on a video

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screen. That is, the realism that Hon focuses on is provided by the image that is displayed to the user on a video display. In fact, Hon displays to the user actual images collected from real patients corresponding to a particular simulated procedure. If the procedure is a simulated insertion of an endoscope into the upper gastrointestinal tract, then recorded images of human upper gastrointestinal tracts are displayed to the user. Hon specifically notes that the actual model need not be particularly realistic: *"...without the necessity of a realistic look to the model...*(see column 7, line 63)." Hon specifically teaches that realistic simulated physiological structures are not important, because actual images of real patients will be displayed to the user, and it is the image being displayed that is key to Hon's invention. One purpose behind applicant's use of a conductive elastomer is to enable a more realistic and effective training model to be achieved. Given Hon's teachings, it does not appear that an artisan of ordinary skill in the art would have been motivated to use a conductive elastomer to achieve a more realistic model.

Because there appears to be no motivation to combine the references as suggested by the Examiner, absent the application of impermissible hindsight, a *prima facie* case of obviousness cannot be supported. Because applicant appears to be the first person to incorporate conductive elastomers into simulated physiological structures, or into training devices that include simulated physiological structures, and more importantly, the first to recognize the benefits of such a combination, applicant is entitled to relatively broad claims. Accordingly, the rejections of Claims 1-3, 7-9, 15, 16, 20-22, 31, 32, 34, 35, 45, 47-54, 56-61, 74-82, and 85 under 35 U.S.C. §103 as being obvious over Hon in view of D'Antonio should be withdrawn.

Claim 8 specifically recites that the evaluation circuit comprises a capacitance sensitive switch. The specification describes capacitance sensitive switches in detail in connection with FIGURE 11E (see the text beginning in the last paragraph of page 41, and continuing through page 43). Capacitance sensitive switches are configured to determine when a surface is touched by an object, such that the touch *changes the capacitance of the switch*. The Pressex switch disclosed by D'Antonio does not appear to be a capacitance sensitive switch. Instead, the Pressex material appears to be a resistant sensitive switch that includes closely adjacent contacts, at least one of which can be deflected to close the circuit. Simply because the circuit into which the Pressex material is incorporated includes both resistors and capacitors does not merit a conclusion that the circuit

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disclosed by D'Antonio is a switch that responds when touched by an object that changes the capacitance of the switch. Claim 8 further distinguishes over the cited art for this additional reason.

Claim 15 specifically recites that the evaluation circuit is configured to close when a particular portion of the simulated physiological structure is manipulated. Hon discloses simulated physiological structures that incorporate sensors configured to detect the position of a simulated medical instrument. Evaluation circuits including sensors configured to detect the position of instrument are simply not equivalent to evaluation circuits configured to open or close when a particular portion of a simulated medical physiological structure is manipulated. Hon's evaluation circuits do not require physical manipulation of the simulated physiological structure. D'Antonio does not provide any teachings that would lead one of ordinary skill in the art to modify Hon's evaluation circuits to achieve an equivalent evaluation circuit. Claim 15 further distinguishes over the cited art for this additional reason.

Claim 21, 61 and 74 specifically recite an indicator that *provides an indication of whether the medical devices are properly utilized to perform the simulated medical procedure*. As described in the specification as filed, such an indicator provides a "grade" or indication of the user's performance. Neither Hon nor D'Antonio discloses such an element, and thus a rejection based on the combination of Hon and D'Antonio is not appropriate.

Claims 32 and 82 specifically recite a physiological control element configured to produce a simulated physiological response based on a signal from the evaluation circuit. As described in the specification as filed, such simulated physiological responses can encompass, for example, a change in a simulated heartbeat, a change in a simulated respiratory rate, or a simulated muscle contraction/activation. In other words, the simulated physiological structure/model physically responds to a stimulus. Neither Hon nor D'Antonio appears to teach or suggests such an element. Claims 32 and 82 further distinguish over the cited art for this additional reason. Claim 78 similarly recites determining a physiological response for the medical training simulator to emulate, and further distinguishes over the cited art for substantially the same reasons.

Claim 50 specifically recites that the evaluation circuit conveys a potential the triggers activation of the light source. That is, the evaluation circuit is directly responsible for energizing the light source. Hon does disclose providing a video during training; however, that video feed is not energized by the evaluation circuit. The modifications required to achieve an equivalent invention

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are not taught by the cited art, nor does there appear to be any motivation that would have led one of ordinary skill in the art to perform such a modification. Claim 50 further distinguishes over the cited art for this additional reason.

Claim 53 specifically recites that the evaluation circuit is configured to respond to the proper execution of a simulated medical procedure that requires *the removal of a non-conductive portion of the evaluation circuit, so that conductive portions of the evaluation circuit are coupled together to complete the circuit.* The cited art simply does not teach or suggest any equivalent evaluation circuit. There is simply no evidence, other than the application of impermissible hindsight, that an artisan of ordinary skill would have been motivated to modify Hon's training apparatus to include an evaluation circuit which responds only when a user correctly removes a non-conductive portion of the evaluation circuit in a simulated medical procedure. Claim 53 further distinguishes over the cited art for this additional reason.

Claim 75 specifically recites that an indication of the user's performance during a simulated procedure is provided to another party, such that the user of the training device is unaware of the indication during the execution of the simulated procedure. The cited art does not teach or suggest grading a user's performance, and shielding that grade from the user during execution of the simulated medical procedure. Hon simply discloses providing a video feed of recorded images from actual patients corresponding to a particular simulated procedure. The cited art simply does not teach or suggest generating a performance indication that is hidden from the user. There is simply no evidence, other than the application of impermissible hindsight, that an artisan of ordinary skill would have been motivated to modify Hon's training apparatus to achieve an equivalent invention. Claim 75 further distinguishes over the cited art for this additional reason.

Claims 77 and 81 specifically recite that an indication of the user's performance during a simulated procedure is used to determine a rate of learning, while Claim 80 specifically recites a processor configured to implement the function of comparing the score for a simulated procedure to at least one score from a previous simulated procedure. Neither Hon nor D'Antonio disclose such elements, and thus a rejection based on the combination of Hon and D'Antonio is not appropriate.

Obviousness Rejection Based on a Combination of D'Antonio, Hon and Pugh

The Examiner has rejected Claim 23 under 35 U.S.C. §103 as being obvious over Hon (U.S. Patent No. 4,907,973) in view of D'Antonio (U.S. Patent No. 5,510,605), further in view of Pugh

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(U.S. Patent No. 6,428,323). The Examiner recognizes that neither Hon nor D'Antonio discloses a meter, and notes that Pugh discloses the missing meter, and concludes it would have been obvious to one of ordinary skill in the art to combine the elements to achieve an equivalent invention. Applicant respectfully disagrees for the following reasons.

Generally as discussed above, the combination of Hon and D'Antonio does not appear to support a *prima facie* case of obviousness, because D'Antonio is not analogous art, and more importantly, because there appears to be no motivation, absent the application of impermissible hindsight, to modify the references as required to achieve an equivalent of what is recited in the claims. Dependent claims are patentable for at least the same reasons as the claims upon which they depend, thus Claim 23 is patentable for the same reasons as independent Claim 2, upon which it ultimately depends. Accordingly, the rejection of Claim 23 as being obvious over Hon in view of D'Antonio and Pugh should be withdrawn.

Obviousness Rejections Based on a Combination of D'Antonio, Hon and Niiranen

The Examiner has rejected Claims 24, 25, 43, and 44 under 35 U.S.C. §103 as being obvious over Hon (U.S. Patent No. 4,907,973) in view of D'Antonio (U.S. Patent No. 5,510,605), further in view of Niiranen (U.S. Patent No. 2,871,579). The Examiner recognizes that neither Hon nor D'Antonio discloses a simulated tissue structure, but notes that Niiranen discloses the missing element and concludes that it would have been obvious to one of ordinary skill in the art to combine the elements to achieve an equivalent invention. Applicant respectfully disagrees for the following reasons.

Generally as discussed above, the combination of Hon and D'Antonio does not appear to support a *prima facie* case of obviousness, because D'Antonio is not analogous art, and more importantly, because there appears to be no motivation, absent the application of impermissible hindsight, to modify the references as required to achieve an equivalent invention. Dependent claims are patentable for at least the same reasons as the claims upon which they depend, thus Claims 24, 25, 43, and 44 are patentable for the same reasons as the independent claims upon which they depend. Accordingly, the rejection of Claims 24, 25, 43, and 44 as being obvious over Hon in view of D'Antonio and Niiranen should be withdrawn.

Claim 44 specifically recites a training simulator comprising an *exterior cover encompassing a substantial portion of the surgical trainer, the exterior cover having* ***at least one predefined***

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***opening defining an operative site**, so that each opening is disposed adjacent to a different structure, to facilitate access to said structure.* Such a configuration can readily be seen in FIGURE 5, which includes a predefined opening proximate to the throat, the chest, and the stomach. Applicant recognizes that Niiranen discloses a simulated tissue structure; however, the cited art does not teach the recited predefined opening. Niiranen includes a skin layer that is incised to gain access to lower portions of the tissue structure. No predefined opening is present. There is simply no evidence, other than the application of impermissible hindsight, that an artisan of ordinary skill would have been motivated to modify the cited art to achieve an equivalent of the recitation of this claim. Claim 44 further distinguishes over the cited art for this additional reason.

Obviousness Rejections Based on a Combination of D'Antonio, Hon and Talmage

The Examiner has rejected Claims 26-28, 55, and 86 under 35 U.S.C. §103 as being obvious over Hon (U.S. Patent No. 4,907,973) in view of D'Antonio (U.S. Patent No. 5,510,605), further in view of Talmage (U.S. Patent No. 4,687,885). The Examiner recognizes that neither Hon nor D'Antonio discloses an evaluation circuit implemented in three dimensions, notes that Talmage discloses the missing element, and concludes it would have been obvious to one of ordinary skill in the art to combine the elements to achieve an equivalent invention. Applicant respectfully disagrees for the following reasons.

Generally as discussed above, the combination of Hon and D'Antonio does not appear to support a *prima facie* case of obviousness, because D'Antonio is not analogous art, and more importantly, because there appears to be no motivation, absent the application of impermissible hindsight, to modify the references as required to achieve an equivalent of what is recited in the claims. Dependent claims are patentable for at least the same reasons as the claims upon which they depend, thus Claims 26-28, 55, and 86 are patentable for the same reasons as they independent claims upon which they depend. Accordingly, the rejection of Claims 26-28, 55, and 86 as being obvious over Hon in view of D'Antonio and Talmage should be withdrawn.

Claim 28 specifically recites a training simulator including an evaluation circuit implemented as a three-dimensional grid that encompasses ***a majority of a simulated physiological structure***. While Talmage suggests a three-dimensional grid, the cited art simply does not teach or suggest that such a three-dimensional grid should encompass substantially all of the simulated physiological structure incorporated into a training simulator. There is simply no evidence, other than the

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application of impermissible hindsight, that an artisan of ordinary skill would have been motivated to modify the cited art to achieve an equivalent invention. Claim 28 further distinguishes over the cited art for this additional reason.

Obviousness Rejections Based on a Combination of D'Antonio, Hon and Szinicz

The Examiner has rejected Claims 29, 30, 33, 83, and 84 under 35 U.S.C. §103 as being obvious over Hon (U.S. Patent No. 4,907,973) in view of D'Antonio (U.S. Patent No. 5,510,605), further in view of Szinicz (U.S. Patent No. 5,425,644). While the Examiner recognizes that neither Hon nor D'Antonio discloses a plurality of fluid channels, a servo or a pump, he notes that Szinicz discloses the missing elements and concludes that it would have been obvious to one of ordinary skill in the art to combine the elements to achieve an equivalent of applicant's claim recitation. Applicant respectfully disagrees for the following reasons.

Generally as discussed above, the combination of Hon and D'Antonio does not appear to support a *prima facie* case of obviousness, because D'Antonio is not analogous art, and more importantly, because there appears to be no motivation, absent the application of impermissible hindsight, to modify the references as required to achieve an equivalent invention. Dependent claims are patentable for at least the same reasons as the claims upon which they depend, and thus, Claims 29, 30, 33, 83, and 84 are patentable for the same reasons as the independent claims upon which they depend. Accordingly, the rejection of these claims as being obvious over Hon in view of D'Antonio and Szinicz should be withdrawn.

Claim 29 specifically recites a training simulator including an evaluation circuit including a conductive elastomer, at least a portion of which is incorporated into at least some of the integral fluid channels. Even if, *arguendo*, as suggested by the Examiner, it would have been obvious to incorporate integral fluid channels into Hon's device, the cited art does not teach or suggest that the conductive elastomer-based evaluation circuit should be integrated into at least a portion of the integral fluid channels. A fluid channel comprising an evaluation circuit is simply not taught or suggested by the cited art. There is no evidence, other than the application of impermissible hindsight, that an artisan of ordinary skill would have been motivated to modify the cited art to achieve an equivalent of what is recited in the claim. Claim 29 further distinguishes over the cited art for this additional reason.

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Claim 30 specifically recites a training simulator including an evaluation circuit including a conductive elastomer, at least a portion of which is incorporated into at least some of the integral fluid channels, ***such that the evaluation circuit provides a signal if such a fluid channel is damaged during the simulated procedure***. In Szinicz's apparatus, if a fluid channel is cut, simulated blood will flow from the cut channel. There is no teaching that an evaluation circuit should be incorporated into the fluid channel to provide an indication as to whether the fluid channel has been damaged. There is no evidence, other than the application of impermissible hindsight, that an artisan of ordinary skill would have been motivated to modify the cited art to achieve an equivalent invention. Claim 30 further distinguishes over the cited art for this additional reason.

Claim 84 specifically recites a training simulator including a servo configured to move at least a portion of the simulated physiological structure to implement a simulated physiological response, based on information provided to the controller by the conductive elastomer based evaluation circuit. In Szinicz's apparatus, a pump and mechanical apparatus are provided to cause simulated blood to flow through a simulated physiological structure such as a vein. Significantly, the blood flow is not under the control of a controller configured to respond to an evaluation circuit (the pump is simply on). If the user cuts into a simulated artery or vein, the pressure in the fluid channel provided by the pump causes blood to flow out of the cut fluid channel. There is no movement of the simulated physiological structure induced by a servo in response to data from the evaluation circuit. There is no evidence, other than the application of impermissible hindsight, that an artisan of ordinary skill would have been motivated to modify the cited art to achieve an equivalent invention. Claim 84 further distinguishes over the cited art for this additional reason.

Obviousness Rejections Based on a Combination of D'Antonio, Hon, and Leight

The Examiner has rejected Claims 37-41 and 87 under 35 U.S.C. §103 as being obvious over Hon (U.S. Patent No. 4,907,973) in view of D'Antonio (U.S. Patent No. 5,510,605), further in view of Leight (U.S. Patent No. 6,675,757). Although neither Hon nor D'Antonio discloses a plurality of in a neural network or a simulated joint, the Examiner relies upon Leight for disclosing the missing elements and concludes that it would have been obvious to one of ordinary skill in the art to combine these references to achieve an equivalent of the recitation in applicant's claims. Applicant respectfully disagrees for the following reasons.

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As discussed above, the combination of Hon and D'Antonio does not support a *prima facie* case of obviousness, because D'Antonio is not analogous art, and more importantly, because there appears to be no motivation, absent the application of impermissible hindsight, to modify the references as required to achieve an equivalent of applicant's recited matter. Dependent claims are patentable for at least the same reasons as the claims upon which they depend. Thus, Claims 37-41 and 87 are patentable for at least the same reasons as the independent claims upon which they depend. Accordingly, the rejection of these claims as being obvious over Hon in view of D'Antonio and Leight should be withdrawn.

Conclusion

In view of the amendments and the remarks submitted above, it should be apparent that all of the claims now submitted define patentable subject matter that is neither anticipated nor obvious in view of the prior art cited. Therefore, the Examiner is requested to issue the present patent. If there are any questions that might be addressed by a telephone interview, the Examiner is invited to telephone the undersigned attorney, at the number listed below.

Respectfully submitted,

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